Orbital Wall Fracture Repair Using Seprafilm

Mehryar Taban, M.D., Tanuj Nakra, M.D., Ronald Mancini, M.D., Raymond S. Douglas, M.D., Ph.D., and Robert A. Goldberg, M.D.

Department of Orbital and Plastic Reconstructive Surgery, Jules Stein Eye Institute, David Geffen School of Medicine at UCLA, Los Angeles, California, U.S.A.

Purpose: Seprafilm is a hybrid product of carboxymethylcellulose and sodium hyaluronate that can act as an absorbable barrier to decrease the formation and severity of postoperative adhesions in abdominal, thoracic, and pelvic surgeries. The authors report their experience with use of Seprafilm in "trap door" orbital wall fracture repair.

Methods: Retrospective case series of 4 consecutive patients with trap door orbital wall fractures secondary to blunt trauma with entrapped orbital soft tissue who underwent surgical repair with placement of Seprafilm implant in 2008. Orbitotomy was performed via standard transconjunctival and/or transcaruncular approaches with release of entrapped tissues, and placement of Seprafilm implant over the fracture site without fixation. Patients were followed for at least 6 months. Ophthalmic and orbital examinations, including ocular motility and Hertel exophthalmometry measurements, were recorded.

Results: All 6 orbital wall fractures (4 floor, 2 medial wall) were successfully corrected with resolution of restrictive motility in the follow-up period (average 10 months; range 6 months to 1.5 years). Mean patient age was 13.5 years (range, 9–20 years). Two of the 4 patients had 2 separate fractures. There were no complications and no need for reoperation.

Conclusions: Seprafilm may have a role in reconstruction of the "trap door" type of orbital wall fractures. The ease of use, lack of fixation, and absorbable properties without inflammation are encouraging for further study.

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Orbital fractures in children and adolescents are often of the "trap door" type, where a fracture of the orbital wall by a concussive force has partial realignment of the fracture site with entrapment of orbital soft tissue. There is no significant orbital volume displacement and thus minimal risk of enophthalmos, but entrapment of orbital tissue and/or extraocular muscle in these fractures can necessitate urgent surgical repair to release entrapped tissue and place an implant or barrier on the fractured site. Various alloplastic materials have been used including Medpor, Silastic, Teflon, polyamide, methylmethacrylate, titanium, and hydroxyapatite.[1] However, the presence of a foreign body can result in unwanted complications such as infection, extrusion, foreign body reactions, and encapsulation. The disadvantages of autologous materials include donor site morbidity, lengthening of surgical time, and modeling properties of the graft.[1]

Seprafilm (Genzyme Corp., Cambridge, MA, U.S.A.) is a hybrid product of sodium hyaluronate and carboxymethylcellulose that has been modified to enhance product longevity. It has been shown in multiple animal models and clinical studies in humans to decrease the formation and severity of postoperative adhesions in abdominal, thoracic, pelvic and tendon surgeries, by acting as an absorbable barrier.[2–10] It has also been studied in the repair of subtotal tympanic membrane perforation and retinal breaks.[11,12] In the ophthalmic literature, Seprafilm has been shown to significantly reduce postoperative

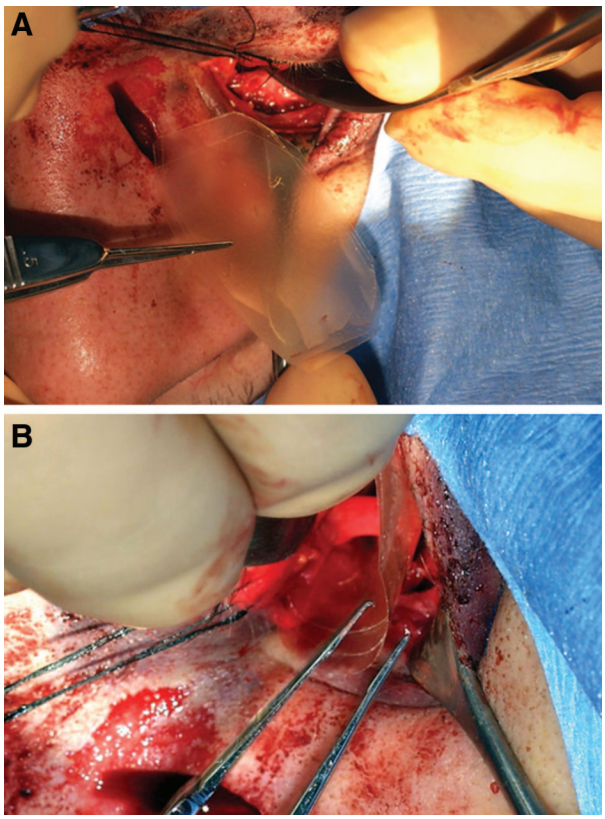

FIG. 1. Intraoperative placement of Seprafilm implant **(A)** (folded in 3 layers) on a trap door orbital floor fracture after release of entrapped tissues **(B)**. This 24-year-old man also had repair of a nasoethmoidal fracture through a modified Lynch incision; he was excluded from our study, but he had successful recovery with full ocular motility postoperatively.

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Address correspondence and reprint requests to Robert A. Goldberg, M.D., Jules Stein Eye Institute, 100 Stein Plaza, Los Angeles, CA 90095-7006, U.S.A. E-mail: goldberg@jsei.ucla.edu

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Patients with trap door orbital fractures repaired with Seprafilm implant

Number	Age (years)	Sex	Time to operation	Ocular motility	Preoperative hertel's (relative)	Fracture site	Follow-up time (months)	Resolution of restrictive motility	Complications
1	20	Male	10 days	50% upgaze	1-mm left proptosis	Left floor	6	Yes	None
2	14*	Male	14 days	75% upgaze	Equal	Left floor	8	Yes	None
3				50% lateral gaze		Left medial wall		Yes	None
4	11*	Male	2 days	50% lateral gaze	1-mm left proptosis	Left medial wall	8	Yes	None
5				75% upgaze		Left floor			
6	9	Male	Same day	50% upgaze	1-mm left proptosis	Left floor	18	Yes	None

*Two patients had 2 separate fractures.

adhesions between the conjunctiva, muscle, and sclera after strabismus surgery.[13]

In this study, we report the use of Seprafilm in "trap door" orbital wall fracture repair, to cover the fracture site and minimize adhesions.

METHODS

After approval by the UCLA Institutional Review Board, a retrospective review was conducted of all orbital fracture cases secondary to blunt trauma between 2005 and 2008, in which Seprafilm was placed intraoperatively. This study reflects the experience of multiple surgeons. Orbitotomy was performed via standard transconjunctival and/or transcaruncular approaches, release of entrapped tissues, and placement of Seprafilm implant over fractured site without fixation (Fig. 1). Seprafilm is provided in a thin sheet (15 × 13 cm), and in this study was folded to create 3 to 4 layers, and then trimmed to fit over the fractured site, resting on bony edges. The medical records were reviewed for patient demographics, medical history, operative details, and follow-up. Patients were followed for more than 6 months. Ophthalmic and orbital examination results, including ocular motility and Hertel exophthalmometry measurements, were recorded.

RESULTS

Four male patients with 6 "trap door" orbital wall fractures (4 floor, 2 medial wall) were analyzed (Table). All fractures were caused by blunt trauma with restriction of ocular motility and positive forced ductions without significant orbital volume displacement. Time from trauma to surgery was 6.5 days (range, 0–14 days). Mean patient age was 13.5 years (range, 9–20 years). Two of the 4 patients had 2 separate fractures. A representative case is shown in Figures 2 and 3.

All fractures were repaired successfully with resolution of forced ductions intraoperatively and resolution of diplopia in the

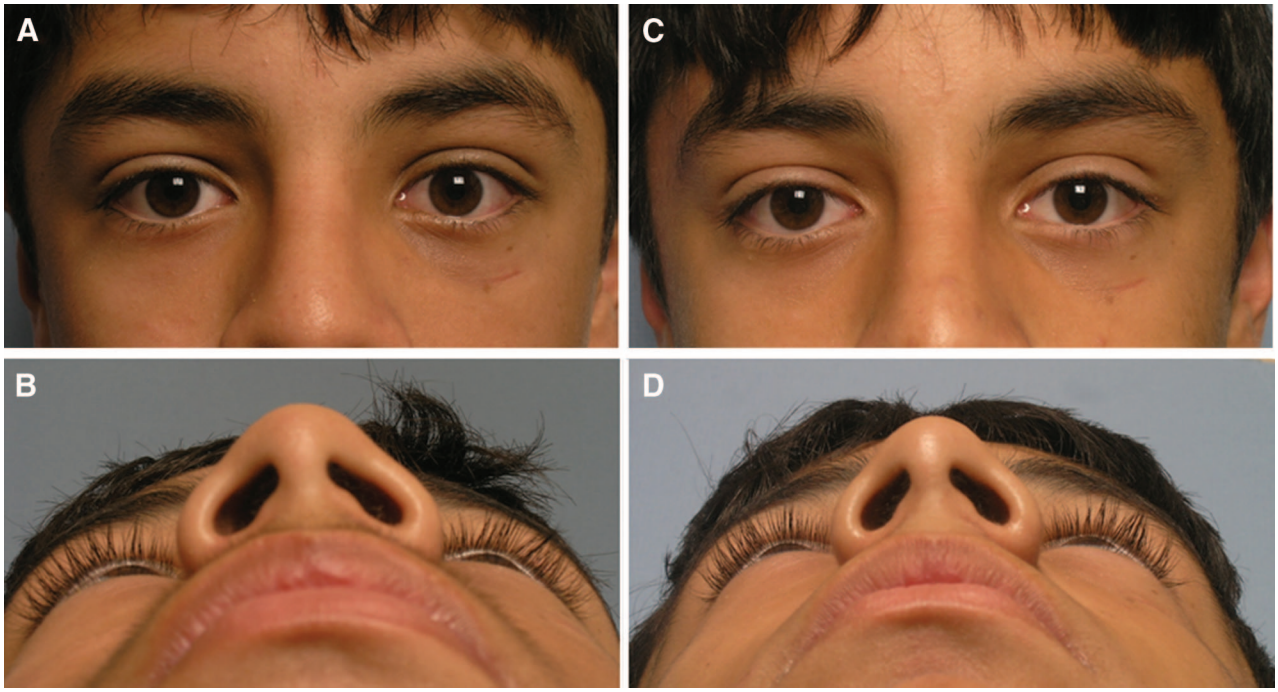

FIG. 2. External photographs of an 11-year-old boy who presented 2 days after blunt trauma to the left orbit with diplopia in upgaze and left gaze, with positive forced-duction testing (Table, nos. 4–5). He had only 1 mm of proptosis OS at presentation. On the same day, he underwent successful repair of the fractures with Seprafilm implant, with full ocular motility at follow-up visits. **A** and **B**, Preoperative views; **(C** and **D)** 3 months postoperatively.

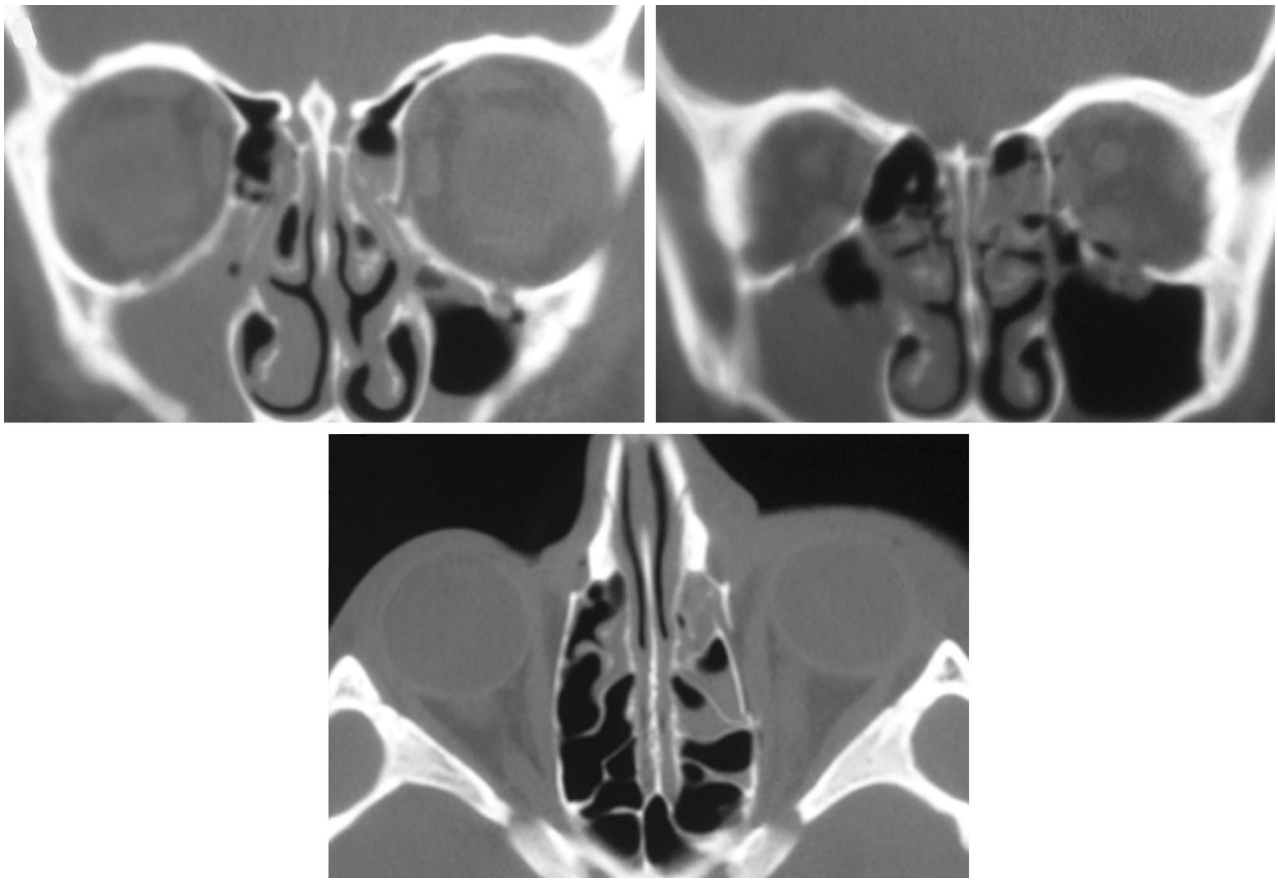

FIG. 3. CT of the same patient as in Figure 2, showing trap door type fractures of the medial wall and floor of the left orbit with entrapped tissue.

follow-up period (average, 10 months; range, 6 months to 1.5 years). There were no complications and no need for reoperation. Hertel exophthalmometry measurements were equal on both sides.

DISCUSSION

In 1996, the U.S. Food and Drug Administration approved Seprafilm as an absorbable barrier to prevent adhesions after abdominal surgery. Its use in other surgical arenas has expanded, both clinically and experimentally, including prevention of postoperative pelvic/gynecological and thoracic/pericardial adhesions, prevention of peritendinous adhesions after flexor tendon injury, prevention of poststrabismus surgery adhesions, and in the repair of subtotal tympanic membrane perforations and retinal breaks.[2–13]

Seprafilm is composed of hyaluronic acid and carboxymethylcelluose that have been modified to increase their persistence in the body. Hyaluronate, a glycosoaminoglycan made of repeating disaccharide units of glucuronic acid and *N*-acetylglucosamine, is a normal constituent of extracellular matrix, connective tissue, synovial fluids, umbilical cord, and vitreous humor.[6,14] Carboxymethylcellulose is a commonly used filler found in food, cosmetics, and pharmaceuticals; it has no known toxic effects and has been shown in animal studies to be effective in reducing postoperative adhesions.[6]

Seprafilm adheres well to wet tissue. In vitro, it remains solid in balanced salt solution for 30 days before it dissolves.[12] In vivo, it turns in a hydrophilic gel approximately 24 hours after placement and provides a protective coat around traumatized tissue for up to 7 days.[4] The biologic mechanisms by which carboxymethylcellulose and modified carboxymethylcellulose exert their efficacy have not been elucidated.[6] In peritoneum, the mesothelium produces hyaluronic acid, which is expressed along the cell membrane and contributes to the pericellular matrix. The primary hyaluronic acid receptor, CD44, is important for hyaluronate-mediated motility. CD44 has been reported to be involved in binding of free-floating cells to hyaluronic acid on the peritoneum. Conditions in which this effect has been observed include endometriosis, ovarian cancer, colorectal cancer, and gastric cancer.[15] It can be speculated that Seprafilm provides enough hyaluronic acid to saturate the CD44 receptor, thus inhibiting intercellular adhesion.[15,16]

The properties of Seprafilm may result from its ability to act as a physical barrier. Gago et al.[14] studied the molecular changes that occur in normal fibroblasts, adhesion fibroblasts, and mesothelial cells as a result of exposure to Seprafilm. They reported that Seprafilm had no effect on biologic markers known to be involved in postoperative adhesion development (transforming growth factor-B1, type I collagen, matrix metalloproteinase-1, matrix metalloproteinase-2, tissue inhibitor of metalloproteinase-1, tissue plasminogen activator) and concluded that the ability of Seprafilm to reduce postoperative adhesions probably stems solely from its action as a physical barrier.[14]

Clinical and experimental studies suggest that Seprafilm is safe and noninflammatory.[2–13] Bülbüller et al.[17] demonstrated that Seprafilm prevented postoperative adhesions without affect-

ing injury recovery. Otake et al.[18] showed that polymorphonuclear neutrophil function is not altered by Seprafilm. Ozkan et al.[13] reported on their use of Seprafilm in strabismus surgery and found no significant difference with regard to inflammation, but there was significantly less fibrosis. In our limited study, we found no unusual inflammation or any complications based on clinical criteria.

Various other products have been tried in attempts to reduce surgical adhesions, including supramide, silicone sleeve, polyglactin 910 mesh, poly(gamma-glutamic acid), cross-linked poly(gamma-glutamic acid), polypeptide sleeve, Interceed, sodium hyaluronate, mitomycin C, and 5-fluorouracil.[13,19] However, none of these products is ideal; some are even toxic.[13,19] Interceed (oxidized regenerated cellulose; Ethicon, Somerville, NJ, U.S.A.) is an FDA-approved membrane that is effective at preventing adhesions but only where there is no blood present, unlike Seprafilm.[7] Seprafilm maintains its efficacy when used with excess irrigation solutions, when layered, and under ischemic conditions.

In our study, Seprafilm was used to cover fracture sites after release of entrapped tissue. All patients had full ocular motility at their latest follow-up visits. The fractures were small and there were no cases of postoperative enophthalmos. No complications were recorded. One patient had concurrent repair of a nasoethmoidal fracture through a Lynch incision, along with repair of the trap door orbital floor fracture (Fig. 1); he was not included in our study, although he had complete recovery of ocular motility postoperatively. Our study is limited by its retrospective, nonrandomized nature, and sample size. However, this pilot study may suggest a role for the use of Seprafilm in orbital surgery.

For small trap door orbital fractures with entrapment, the goal of orbital surgery is to mechanically release entrapped soft tissue from the fracture, to prevent the tissues from prolapsing back through the bony opening, and to prevent restrictive adhesions between the orbital soft tissue and the fracture edges. Permanent implants such as nylon or porous polyethylene satisfy the anatomic requirement, but introduce a permanent foreign body; the subsequent inflammatory response might exacerbate the tendency for fibrosis and scarring. Obviously, atraumatic surgical technique is important in minimizing postsurgical inflammation and fibrosis. Ideally, an implant should separate and support the orbital soft tissues from the fracture site, re-creating normal anatomy, and then dissolve after the bone has healed. It would be desirable if the implant had the ability to participate biologically, for example attenuating the tendency for the orbital soft tissues to react to the injury by making fibrotic scar tissue. Seprafilm may have some of these properties. Our early anecdotal experience, reflected in this case series, is that the material is easy to work with intraoperatively, does not seem to be associated with any unusual swelling, inflammation, or other postoperative complications, and in this small series, was associated with good postoperative motility. If it can reduce postoperative adhesions and resultant restrictive motility problems, it may have a role in other types of orbital surgery such as orbital decompression or complex tumor surgery. Our initial successful experience is encouraging and suggests that additional study of the use of Seprafilm in orbital fracture surgery is warranted.

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